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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,077

Applicant(s)

Fleckenstein et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Part III DETAILED ACTION

Claims 1-29 are currently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5,11, drawn to a semaphorin protein, classified in class 530, subclass 300.
- II. Claims 6-10, 12-18, drawn to isolated nucleic acid, their expression vectors and cells comprising the vector, and method of making a protein of Group I, classified in class 536, subclass 23.1 and class 935, subclass 66.
- III. Claim 19, drawn to method of making a nucleic acid, classified in class 435, subclass 92.1.
- IV. Claim 22 (in part), drawn to an antibody recognizing fragment 179-378 of polypeptide SEQ ID No. 3, classified in class 530, subclass 388.1.
- V. Claim 22 (in part), drawn to an antibody recognizing fragment 480-666 of polypeptide SEQ ID No. 3, classified in class 530, subclass 388.1.
- VI. Claim 22 (in part), drawn to a method of making an antibody to any semaphorin protein, classified in class 424, subclass 130.1.

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VII. Claim 20, drawn to peptide-based methods of screening, classified in class 435, subclass 7.1

VIII. Claims 24,27 drawn to method of treating immunological disorder using polypeptide, classified in class 514, subclass 02

IX. Claims 25,26,28 drawn to method of treating immunological disorder using polynucleotides, classified in class 514, subclass 44.

X. Claim 29, drawn to method of inhibiting inflammation by introducing nucleic acid into a cell, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a polypeptide whereas for Group II the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group I to be directed as to its synthesis by a polynucleotide of Group II, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally,

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polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acids of Group II can be made by methods other than PCR, for example, by chemical synthesis.

Inventions of Groups IV,V are drawn to independent and/or patentably distinct antibodies since each of these products possess different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Additionally, these different groups do not share a common structure which elicits a common activity. The inventions would require non-coextensive structure search and a

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reference teaching one antibody would not teach another antibody.

Inventions VI and IV/V are related as process of making and product made. First, the scopes of the Groups are different as Group VI is drawn to method of making an antibody to any semaphorin protein, not necessarily human semaphorin protein. Second, even if the scope of the Groups had been the same the antibodies of Groups IV, V can be made by other methods, e.g., by producing monoclonal or polyclonal antibodies without using recombinant techniques.

Inventions I or II and IV/V are separate and distinct, as the claims of Inventions I and II are drawn to polypeptides and polynucleotides, respectively, while the claim of groups IV/V is drawn to antibodies. These are differing biochemical entities having differing biochemical properties, structures and effects which would require searching in unrelated areas, and as such, would require an undue burden on the examiner if not restricted.

Inventions I and VII/VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case,

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methods VII/VIII are alternate methods of using the compound of Group I, and the product as claimed can be used in a materially different processes such as generation of antibodies.

Inventions II and IX/X are related as product and processes of use. Methods IX/X are alternate methods of using the compound of Group II, and the product as claimed can be used in a materially different processes such as in hybridization assays.

The methods of groups VII and VIII or IX and X differ in the method objectives, method steps and modes of operation. Further, the methods of groups VII and VIII differ from methods of Groups IX and X in the products used.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

Upon election of any single one of the Groups from above the following election of species is hereby required for the initial search for examination on merits:

If Group I is elected, the claims of the Group are individually or dependently directed to a plurality of disclose patentably distinct species of peptides homologs of peptides SEQ ID No. 3, 4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though the requirement is traversed. In addition, the claims are drawn to either non-modified polypeptide, or to peptides derivatives which are

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either phosphorylated or glycosylated or myristylated. Applicant is required to elect a single disclosed species of each for

- I) one of the polypeptides of SEQ ID No. 3,4, and
- II) polypeptide which is either not modified, or is phosphorylated or glycosylated or myristylated.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The same election of species is applicable if a group drawn to a method of use of polypeptide is elected.

If Group II is elected, the claims of the Group are individually or dependently directed to a plurality of disclose patentably distinct species of polynucleotides of SEQ ID Nos. 1,2,41. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though the requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence

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or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The same election of species is applicable if a group drawn to a method of use of polynucleotide is elected.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

